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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,595	09/19/2003	Timothy A.M. Chuter	BSI-597US	3652

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EXAMINER	
STROUD, JONATHAN R	
ART UNIT	PAPER NUMBER
3774	
MAIL DATE	DELIVERY MODE
01/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/664,595	CHUTER, TIMOTHY A.M.	
	Examiner	Art Unit	
	JONATHAN R. STROUD	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-27 and 29-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-27 and 25-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/04/2008 has been entered.

Response to Arguments

2. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 26-27, 29-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wisselink 6,428,565, further in view of Marcade 5,683,449, further in view of Dehdashitan 6,344,056.

Re claim 1, Wisselink teaches a modular grafting system, col. 3 l1.40-45, col. 4 ll. 59-68, comprising: a main body including a superior end and an inferior end, from which branch blood vessels (e.g., carotid ... subclavian) ... extend", the midsection having an outer diameter that is smaller than an outer diameter of the superior end and an outer diameter of the inferior end - Wisselink teaches self-expanding anchors which would increase the diameter at the superior and inferior end - a first leg and a second leg extending from the main body, col. 4, ll. 50-56 "a bifurcated anatomical conduit (i.e., a conduit having a main portion, a first furcation, and a second furcation)", see also, fig. 2a, or fig, 1f, or fig 1a, and an extension component, col. 4, ll. 1-22, "a branch graft", the extension component being sized to mate with the second leg after placement of the main body within vasculature, col. 4 l1.1-22, "second connector being engageable with said first connector to connect the proximal end of the second pliable tube to the first pliable tube such that fluid which flows through the lumen of the primary graft may pass through said branch opening and into the lumen branch graft.

Wisselink fails to teach a main body with a first transition bridging between the superior end and the midsection and a second transition bridging between the inferior end and the midsection, and further, that specifically either the first or the second transition have respective openings therein with limbs extending therefrom.

Marcade teaches a intraluminal graft fig. 8 with a superior end 750a, a first transition 764 bridging to a midsection 754, bridging to a second transition 756, that then connects to the inferior end, 750b, for the purpose of implantation with a firm connection at either ends and a fluid-tight seal in the midsection.

Marcade fails to teach the branch blood vessels and anchors and branch grafts taught by Wisselink and described above.

Wisselink in view of Marcade fails to suggest placing the branched blood vessels at a first superior transition.

Dehdashitan teaches an endovascular graft that branches from a superior transition zone for the purpose of providing branching blood vessel replacements to maintain a fluid-tight seal where they are needed.

Wisselink teaches the main body further comprising a plurality of stents attached thereto, fig. If, elements 16, "branch grafts", where extension component can be considered either a) the branch grafts 16 or b) the connector portion 17 of the device.

Wisselink teaches the main wherein certain of the plurality of stents are attached to the exterior or interior of the main body, col. 3, II. 60-68, "a primary graft anchoring device ... a radially expandable stent, frame, series of rings, and/or adhesive, sutures, staples, etc ... for holding the graft in place. In the case of sutures or staples, the stents would be attached to the exterior AND interior (through the weaving or interlacing of the element); furthermore, fig. Ib shows the connection occurs at element 42 on the interior, and at ring 48, on the exterior, of the main body.

Wisselink teaches the stents are self-expanding, col. 8, II. 10-15, as are the anchoring elements attached to the ends, which is attached to the inside of the extension component via fixation.

Wisselink teaches at least one stent including structure for attaching the main body to the vasculature, col. 7 I1.65-68, col. 8, II. 1-16.

Wisselink teaches the first leg is sized to extend to and engage an interior surface of a vessel branching from the aortic arch, col. 2 l1.18-35, "depending on which regions of the aorta are involved ... aneurysms involving the aortic arch and the branch arteries ... may be useable for endovascular grafting in regions of a blood vessel (e.g., aorta) from which branch blood vessels (e.g., carotid ... subclavian) ... extend", col. 4, ll. 50-56 "a bifurcated anatomical conduit (i.e., a conduit having a main portion, a first furcation, and a second furcation)".

Wisselink teaches the first leg further including anchoring structure that attaches the first leg within the branch vessel, col. 8, ll. 1-16, "alternatively, they may be formed as separate structures ... self-expanding or pressure-expandable stents ... which are positioned within the lumens of the ...branch grafts to accomplish the desired anchoring."

Wisselink teaches a delivery catheter sized to receive the main body and to be advanced through a branch vessel extending from the aortic arch, col. 8, l1.55-65, "on a balloon catheter or other suitable delivery catheter capable of carrying the primary graft ... and any separate graft anchoring devices) to the intended site of implantation" ... further, col. 8 ll. 33-45 "required a ...graft to be passable through such branch graft openings ... e.g. carotid, subclavian). Wisselink teaches the delivery catheter can include structure for releasing the superior end and second leg of the main body within the aortic arch, and the first leg within the branch vessel, col. 8 ll 55-60, also col. 2 ll. 18-35, "depending on which regions of the aorta are involved ... aneurysms involving the aortic arch and the branch arteries ... may be useable for endovascular grafting in

regions of a blood vessel (e.g., aorta) from which branch blood vessels (e.g., carotid ... subclavian) ... extend". Also see fig. 2a, 2b.

Wisselink teaches a supplemental delivery catheter sized to receive the extension component and to be advanced upstream within an aorta to the aortic arch, col. 9 l1.14-25.

Wisselink teaches the supplemental delivery catheter including a releasing mechanism that accomplishes deploying the extension component at least partially within the second leg of the main body; col. 9 ll. 14-25, balloon can be inflated, causing the purse string suture to break and the branch graft to radially expand, or, snap-fit connection.

Wisselink teaches (in fig. 2c) the extension component 14 further comprising a first anchoring device 40, 42, 46, 48 and a second anchoring device 20, the first anchoring device being sized to engage the second leg of the main body 12a and the second anchoring device being sized to engage interior walls of the aorta 20.

Wisselink teaches the anchoring devices are self-expanding, col. 8, J l1. 1-16, "alternatively, they may be formed as separate structures ... self-expanding or pressure-expandable stents ... which are positioned within the lumens of the branch grafts to accomplish the desired anchoring."

It would have been obvious to one of ordinary skill in the art at the time of invention to modify Wisselink in view of Marcade, in order to provide limited kinking, to reduce the amount of material and the delivery profile therein, and accommodate the wide variety of arterial sizes in patients, and to further modify Wisselink in view of

Marcade in view of Dehdashitan, in order to create a branched prosthesis that provides fluid-tight seals and branched vessels where appropriate while maintaining the advantages of Marcade at the midsection of Marcade's design.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN R. STROUD whose telephone number is (571)270-3070. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 6 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571)272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jonathan R Stroud/
Examiner, Art Unit 3774
/Thomas J Sweet/
Primary Examiner, Art Unit 3774